

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Application of: Seifalian *et al*

Serial No.: 10/586,649

Filed: January 20, 2005

For: POLYMER FOR USE IN CONDUITS, MEDICAL DEVICES AND BIOMEDICAL SURFACE MODIFICATION

DECLARATION

I, Arnold Darbyshire, do hereby declare and state as follows:

1. I am one of the inventors for US patent application no. 10/586,649 and have a thorough knowledge of the invention.
2. I have read US 2005/0010275 A1 of Sahatjian *et al*, and I believe that the differences between the invention claimed in US patent application no. 10/586,649 and the teaching of Sahatjian *et al* is such that the subject matter claimed in US patent application no. 10/586,649 would not have been obvious to a person of ordinary skill in the art prior to the filing date of US patent application no. 10/586,649.
3. As explained in the opening paragraph of the background section of US patent application no. 10/586,649, that application is concerned with prosthetic vascular grafts, e.g. for use in bypass grafting with autologous veins or arteries. One of the key aims when seeking a suitable material for this purpose is to find one with properties that match as closely as possible the properties of the blood vessel, which the graft is intended to mimic. Thus, using a rigid or stiff material causes a compliance mismatch, and US patent application no. 10/586,649 aims to avoid this by providing an elastic material. This is explained in detail in the opening four paragraphs of the background section of US patent application no. 10/586,649.
4. Sahatjian *et al* is concerned with a quite different problem. Thus, as set out in the background section on page 1, Sahatjian *et al* addresses the problem of restriction of the passage of urine from the bladder towards the urethra due to prostate enlargement. Sahatjian *et al* aims to provide a polymer stent to support the urethra and keep it open despite pressure from the enlarged prostate. Naturally, this requires the stent to be rigid. Previous materials used for such stents include metals and the aim of Sahatjian *et al* is to provide a material which can provide a replacement for such a metal stent.
5. Sahatjian *et al* mentions many different types of polymer, all of which are implied to be suitable for use in preparing suitable polymer stents. For instance, dependent claim 13 of Sahatjian *et al* lists fourteen possible options, with significant variation in terms of chemical structure. It seems that the specific chemical composition of the polymer stent is not crucial, so long as the polymer has the requisite physical properties, i.e. sufficient rigidity.

6. . Some of the polymers mentioned in Sahatjian *et al* contain silsesquioxane groups. An example is given at paragraph [0131], which is a copolymer that contains both silsesquioxane-containing segments and polyol-containing segments. The silsesquioxane-containing segments are included simply as chain extenders according to paragraphs [0085], [0087], [0088] and [0089]. Having these bulky groups on side chains of the polymer has an anchoring effect, which reduces the possibility of the copolymer changing shape and makes it more rigid. The more silsesquioxane groups that are present, therefore, the greater the rigidity of the resulting copolymer. Thus, consistent with the requirement for the material to be rigid, paragraph [0131] of Sahatjian *et al* indicates that the number of silsesquioxane-containing segments should be from 1 to 20 times the number of polyol-containing segments.

7. Claim 38 of US patent application no. 10/586,649 is now being limited to require, among other things, that when the siloxane group is a silsesquioxane group, then there must be more polyol segments than siloxane segments. This is clearly different from Sahatjian *et al* which generally has more siloxane segments than polyol segments (at the least, there are the same number of polyol and siloxane segments). The silsesquioxane of 10/586,649 is therefore present in order to modify the properties of the polymer and not as a chain extender as intended by Sahatjian *et al*. Indeed, other materials such as ethylene diamine are used as the chain extender in 10/586,649.

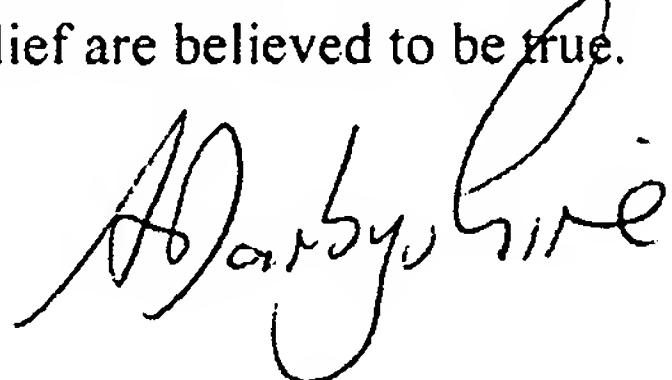
8. On reading Sahatjian *et al*, I do not believe that any skilled person would have contemplated using copolymers with fewer silsesquioxane-containing segments than polyol-containing segments on the basis of Sahatjian *et al*, for the following reasons.

9. Polymers with silsesquioxane groups are just one of many different possible polymer materials mentioned in Sahatjian *et al*. Further, those polymers in Sahatjian *et al* which do include silsesquioxane groups only include silsesquioxane-containing segments as "chain extenders". Accordingly, the skilled person would not have had any reason to believe there would be any beneficial effect to be achieved by experimenting with silsesquioxane groups, and would not have been motivated to use these materials in any way other than as a chain extender.

10. Moreover, rigidity is of fundamental importance to the polymer stents of Sahatjian *et al* in order for them to be fit for their purpose, and so the skilled person would not have considered using copolymers with fewer silsesquioxane-containing segments than polyol-containing segments, for fear of compromising rigidity. He or she would, for instance, have been far more likely to investigate an alternative chain extender group with bulky side groups, and again ensure that segments containing the alternative chain extender group were still in the majority.

11. I acknowledge that wilful false statements and the like are punishable by fine or imprisonment, or both, and may jeopardize the validity of the application or any patent issuing thereon. All statements made of my own knowledge are true and all statements made on information and belief are believed to be true.

Signed



This 22 Day of October 2009.